Arizona State Board of Pharmacy
1700 W. Washington, Suite 250
Telephone (602) 771-2727 Fax (602) 771-2749
www.azpharmacy.gov

NOTICE AND AGENDA OF A MEETING OF THE ARIZONA STATE BOARD OF PHARMACY'S CONTINOUS QUALITY ASSURANCE IN PHARMACIES TASK FORCE

Pursuant to A.R.S, § 38-431.02, notice is hereby given to the members of the Arizona State Board of Pharmacy (Board), the Continuous Quality Assurance Program Task Force (CQAP) and to the general public that the Board's CQAP Task Force will hold a meeting open to the public on:

October 23, 2008 at 1:00 P.M.
Arizona State Board of Pharmacy Meeting Room
1700 W. Washington, Third Floor, Room 312
Phoenix, AZ 85007

One or more members of the Board's CQAP Task Force may participate in the meeting by telephonic communications.

Title 2 of the Americans with Disability Act (ADA) prohibits the Board from discriminating on the basis of disability in its public meetings. Persons with a disability may request a reasonable accommodation by contacting Cheryl Frush, Deputy Director at (602) 771-2735. Requests should be made as early as possible to allow time to arrange the accommodation.

During the course of the meeting, the Board's CQAP Task Force, upon a majority vote of a quorum of the members, may hold an executive session for the purposes of obtaining legal advice from the Board's attorney on any matter listed on the agenda pursuant to A.R.S. § 38-431.03 (A) (3). The executive session will be held immediately after the vote and will not be open to the public.

The agenda is subject to change up to 24 hours prior to the meeting. The Task Force Chair reserves the right to change the order of the items on the agenda, except for matters set for a specific time.

AGENDA

The Agenda for the meeting is as follows:

Call to Order – Ridge Smidt, Pharm.D., Chair

1. **Discussion and Approval of Task Force Minutes – February 27, 2008 meeting**

2. **Discussion and Review of the proposed draft rules for the Continuous Quality Assurance Program in Arizona and possible recommendations to the Board concerning the proposed rules**
   - **A. Review of Memorandum regarding the drafting and understanding of the Continuous Quality Assurance Program rules**
   - **B. Review of Task Force's recommendations of proposed rules to the Board**
   - **C. Review of the Arizona Community Pharmacy Committees recommendations to the Task Force and Board concerning proposed rules**

3. **Call to the Public**
   The Task Force may make an open call to the public during the meeting, subject to reasonable time, place, and manner restrictions, to allow individuals to address the Task Force on any issue within its jurisdiction. Pursuant to A.R.S. § 38-431.01 (G), members of the Task Force are not allowed to discuss or take legal action on matters raised during an open call to the public unless the matters are properly noticed for discussion and legal action. However, the Task Force may ask staff to review a matter or may ask that a matter be placed on a future agenda.

4. **Adjournment**

Prepared and Posted 10/20/2008CF

Arizona State Board of Pharmacy
1700 W. Washington, Suite 250
Phoenix, AZ 85007
Telephone (602) 771-2727 Fax (602) 771-2749
www.azpharmacy.gov

THE ARIZONA STATE BOARD OF PHARMACY'S CONTINUOUS QUALITY ASSURANCE IN PHARMACIES TASK FORCE HELD A MEETING FEBRUARY 27, 2008 AT THE ARIZONA STATE BOARD OF PHARMACY OFFICE

MINUTES FOR MEETING

AGENDA ITEM 1 – Call to Order – February 27, 2008

Chair Dr. Berry convened the meeting at 1:00 P.M. and welcomed everyone to the meeting. The following task force members were present: Ken Baker, Misty Vo, Dan Milovich, Sarju Patel, Mindy Rasmussen, Mark Boesen, Janet Elliot, Ridge Smidt, Hal Wand, and Cheryl Frush.

AGENDA ITEM 1 – Approval of Minutes

Following a review of the minutes and an opportunity for questions and **on motion by Dr. Smidt and seconded by Mr. Milovich,** the minutes of Task Force Meeting held on February 27, 2008 were unanimously approved by the Task Force Members.

AGENDA ITEM 2– Discussion and Review of the proposed draft rules for the Continuous Quality Assurance Program in Arizona and possible recommendations to the Board concerning the proposed rules

Chair Dr. Berry opened the discussion by asking Ms. Rasmussen and Mr. Baker to address the Task Force concerning the proposed draft.

Mr. Baker stated that the proposed draft defines Quality related events and errors. Mr. Baker specified that the task force members felt that quality related events are near misses and should be tracked.

Ms. Elliott stated that the Arizona Community Pharmacy Committee does not support the tracking of near misses. Ms. Elliott stated that each pharmacy should determine what information they would like to track.

The Task Force Members discussed what errors they felt should be tracked. The Task Force Members also discussed the reasons for the tracking of various events.

After much discussion, the task force members decided to continue to work on the proposed draft rules.

At this time, another meeting was not scheduled. It was decided that the task force members would continue to work on the proposed draft and a meeting would be scheduled in the future to review the draft and make appropriate recommendations to the Board.

AGENDA ITEM 4 – Call to the Public

Chair Dr. Berry announced that interested parties have the opportunity at this time to address issues of concern to the Task Force; however the Task Force may not discuss or resolve any issues because the issues were not posted on the meeting agenda.

AGENDA ITEM 5 – Adjournment

There being no further business to come before the Task Force, **on motion by Mr. Milovich and Mr. Patel,** the Board unanimously agreed to adjourn the meeting at 2:30 P.M.

A Memorandum regarding the drafting and understand of

TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 23. BOARD OF PHARMACY
R4-23-622. Continuous Quality Improvement Program

Every pharmacist and every technician knows that errors occur within the practice of pharmacy. Any pharmacist or technician who is not acquainted with the sinking, sick feeling that comes from the realization that a medication error has occurred and that they are at least partially responsible, has not practiced pharmacy long enough and has not yet filled enough prescriptions. Every one makes errors and no one wants to make another.

As difficult as a medication error is on the professional, it is more difficult for the patient and the patient's loved ones. Prescription drugs are restricted to "prescription only" status because they are powerful chemical agents and each carries risks of side effects and unwanted actions. Each can be a wonder-drug and each can bring with it a nightmare. Most of these risks and reactions can be anticipated and steps can be taken to avoid or minimize them.

There is a level of risk associated with prescription drugs that is not anticipated and cannot always be planned for – the risk of an error made by the trained professional whose job it is to safeguard against such an error. Such risks can be avoided and, at least theoretically, should never happen. And yet they do.

The Arizona legislature attempted to reduce this risk of harm caused by medication errors when it enacted ARS § 32-1973, mandating that each pharmacy in Arizona implement a continuous quality assurance program. This patient safety legislation required, in part:

> A. As prescribed by the board by rule, each pharmacy shall implement or participate in a continuous quality assurance program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors. The rules shall prescribe requirements to document compliance and any other provisions necessary for the administration of the program.

In order for a quality program to continuously improved and evolve, it is necessary to learn from past mistakes. The pharmacy needs to know where its vulnerabilities for future errors reside before the next error occurs so that steps can be taken to avoid them. One necessary step

that must be taken in order to reduce the risk of medication errors is to record and document mistakes and errors. Anticipating that one of the problems in implementing a quality program is the reluctance of the part of pharmacists, technicians and pharmacy owners to honestly record such mistakes for fear its own words will be used as evidence of its failures and used against it in legal proceedings, the legislature also provided protection for such records.

> *B. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding. This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated only as a component of a pharmacy's ongoing quality assurance program and maintained only for that program.*

The legislature exempted hospitals and other organizations that are nationally accredited from this legislation.

> *C. A pharmacy meets the requirements of this section if it holds a current general, special or rural general hospital license from the department of health services and is any of the following:*
>
> *1. Certified by the centers for medicare and medicaid services to participate in the medicare or medicaid programs.*
>
> *2. Accredited by the joint commission on the accreditation of health care organizations.*
>
> *3. Accredited by the american osteopathic association.*

The Arizona Board of Pharmacy asked individuals and organizations interested in this legislation to serve on a committee to draft the rules implementing the legislation.[1] Members of the Board also participated, but their involvement was limited to public, announced meeting, all held in the Board of Pharmacy hearing room. Dean Wright, the board legislative expert worked with the committee on language and form. Minutes of all public meeting are available from the Board of Pharmacy.

In drafting the proposed rules, five new definitions were incorporated within the rule.

> ***R4-23-110. Definitions***
>
> ***"Continuous quality improvement program" or "CQI program" or "continuous quality assurance program"*** *means a planned process designed by a pharmacy permittee to identify, evaluate, and prevent medication errors.*

While the underlying statute used the term Continuous Quality Assurance Program, the term Continuous Quality Improvement or CQI is purposefully substituted in the rules. This was done to avoid confusion and misunderstanding. Terms and acronyms commonly used, QA, CQI, TQM, and others are viewed as synonymous. CQI, however, is seen as more descriptive and more in keeping with the current vocabulary used within pharmacy. A CQI program is a quality assurance program, but portrays more accurately and with more universal understanding the nature of the plans. All strive to assure the absence of all medication errors in pharmacy, but all know that perfection is an unlikely result of any plan. The quality plans actually envisioned and attainable are those that continuously evolve and improve. While the goal stated in the legislation is to prevent medication errors, the best programs reduce the risk of a medication error reaching the patient. For that reason, programs must continuously improve.

> ***"Medication error"*** *means any unintended variation from a prescription or drug order. Medication error does not include any variation that is corrected prior to dispensing the medication to the patient or patient's agent, or any variation allowed by law.*

There are many ways to define the term medication error. In pharmacy the most useful is a mistake or "unintended variation from a prescription or drug order" that reaches a patient. A mistake that does not reach the patient is a success. The program or quality system worked. In most systems, including NASA, it is referred to as a "near-miss". In addition, a prescription or drug order may be intentionally modified or changed. Usually such changes are for the benefit of the patient and according to law. As such they are not within the definition of medication error.

> ***"Quality-related event" or "QRE"*** *means both:*
>
> *A medication error as defined in this section, or*
>
> *An occurrence during one part of the prescription process that would have resulted in a medication error except that intervention by a pharmacy staff member at another part of the prescription process prevented delivery of the potential medication error to the patient or care-giver.*

Several years ago it was recognized that a term was needed in pharmacy to describe all mistakes made during the filling of prescription or drug order. Merely referring to these as "mistakes" was at times confusing. The term coined to include both mistakes that were caught before they reached a patient, also called a near-miss, and medication errors was a quality related event or QRE. The term has proved useful. Unfortunately, in a few instances, statutes in some

states have used the term quality related event or QRE as synonymous with the term medication error. The Arizona definition makes clear that QRE includes both near-misses and medication errors. This is important because of the two methods of monitoring programs that are recognized in the rules.

It is recognized that not every mistake would qualify as a quality related event that required documentation and reporting. Too inclusive a definition could be equally detrimental as too narrow a definition. A technician the momentarily picks up the wrong package from the shelf, immediately notices the mistake and exchanges it for the correct package, would not be expected to report this as a QRE. The definition indicates that a mistake qualifies as a QRE or near-miss only if it passes undetected and uncorrected from one process, e.g. filling, to another. In the example here, the picking of the wrong package would only amount to a QRE if it were not caught until the filling process had been completed.

While human programs will never attain perfection, they can evolve to march continuously toward the goal of perfection – the elimination of medication errors. In order for a quality pharmacy program to constantly improve it must incorporate a monitoring system that documents gross imperfections and periodically studies and applies recorded information to make changes in the quality program that will reduce the risk of future errors.

No one system of monitoring works best for all pharmacies. The most beneficial program of monitoring is the one that fits the operations of a particular pharmacy. For a governmental body to attempt to force one system onto every pharmacy is likely to result, in at least some situations, in the opposite of what was intended. These rules require a monitoring program, but allow each pharmacy or group of pharmacies, to use the system that best works for it.

This monitoring requirement may be met through the implementation of either or a combination of two broadly defined programs that have proved useful in pharmacy. Each program has advantages and each has disadvantages. Each has its advocates and each is recognized by the Institute of Medicine. Many pharmacies will use a combination of both systems. Importantly, the monitoring system will be modified by the pharmacy or group to meet its own needs and requirements.

Pharmacies may meet the requirements of this section (R4-23-622) by adopting a QRE monitoring program, a peer review error monitoring program or a combination of each. As circumstances, attitudes, or opinions change pharmacies may at a later date modify its program or change its system entirely. As long as the rule is met and the goal is reduction of medication errors, a reasonable amount and type of experimentation should be encouraged. It is hoped that lessons learned will be shared throughout the profession.

> ***"Quality-related event monitoring program" or "QRE Monitoring Program"*** *means:*
>
> *A system of recording, summarizing, and analyzing quality-related events, including medication errors and other occurrences within the definition of QRE in this section. A QRE monitoring program uses statistical process controls and analysis to discover and reduce the risks of vulnerabilities within the prescription process before quality related events and medication errors occur. QRE Monitoring Programs use large numbers of near-misses and errors (QRE) to determine through a statistical analysis what mistakes are most likely and how those risks can be reduced.*

A QRE monitoring program uses larger numbers by recording very select information concerning each quality related event. The vast majority of quality related events are caught before delivery to a patient (near-miss), so the numbers recorded are larger. By documenting each medication error plus each near-miss, the pharmacy can review not just the mistakes that actually reach a patient, but all detected variations occurring in the system. Some say this approach is more proactive because it works to reduce the risk of a mistake being made before it is received by a patient and before it becomes an error.

Less information is collected for each QRE and the information is more selective. Because of the numbers of QREs recorded, the system uses statistics and may be designed to make the recording process easier and simpler. Only basic information is captured and that in a form that allows statistical representation of vulnerabilities. It is generally considered that in a useful system information on each QRE should be able to be recorded in no more than thirty to forty seconds. The collected information shows where in the prescription filling process the QRE occurred; the nature of the QRE; drugs involved; the day and date; where the QRE was discovered and whether or not it reached the patient. Experience shows that if more information is attempted to be collected, the system begins to fail and the amount of information actually

decreases. In addition, more information does not necessarily result in better use of the data and improvement in the system.

Since this system uses statistics, the captured information is placed into a spread sheet and usually presented in graph or table format. On a regular, periodic schedule, the information is studied for vulnerabilities and one, or at most two, areas of concentration are selected as a focus for improvement over the next time period. For example, a pharmacy that discovers that a large percent of its QREs for a month involved typing directions on the label incorrectly, may decide that for the next thirty days all members of the pharmacy staff are to concentrate on being certain the label is correct for each prescription or drug order. New techniques or best practices are added to the program or re-emphasized to prevent the event from occurring in the first place or to assure the mistake is detected and corrected before it reaches the patient. At the end of thirty days, progress is measured and posted for all to review. For the next month, another vulnerability is attacked in a similar manner. By contrast a peer review monitoring program collects more information on fewer events – only errors that reach a patient.

> ***Peer Review error monitoring*** *program means:*
>
> *A system of recording and reviewing each medication error applying root cause analysis to each medication error. A Peer Review Error Monitoring Program shall analysis, collectively and individually, medication errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent or reduce the risk of a recurrence.*

A peer review error monitoring program is generally considered the more traditional approach to continuous quality improvement. Information is documented only on actual medication errors. Each medication error is studied in some depth to determine what happened, when and where it happened, how it happened and why it happened. A particular error may be studied by an individual or by a group. Once these questions are answered, as in the QRE program, the goal is to review the system to determine what techniques or best practices may be introduced or enforced to avoid the reoccurrence of this particular error in the future. This approach is more retrospective than a QRE monitoring system and some say it is more cumbersome and less likely to be maintained at high level. Others argue peer review error monitoring has the advantage of focusing more on the mistakes that actually reach a patient.

Neither monitoring system is perfect and each work best over time. Many pharmacies will use parts or combinations of both systems. The goal of each is the same and each can assist in constantly improving quality.

At the heart of Arizona Rule R4-23-622 is the requirement that each pharmacy implement or participate in a Continuous Quality Improvement or Assurance Program. As explained earlier, the term improvement is considered more descriptive that assurance, but, regardless of the name used, the goal is to reduce the risk of medication errors in pharmacy. Pharmacists have the skills and ability to enhance a patient's health through the correct use of medication. However, the first duty of each pharmacist may be summed up in the medical admonition, "First, do no harm."

The first four parts of the section, A through D, set forth the basic requirements of the rule. Paragraph A repeats the exception for hospital pharmacies and others that are certified or accredited and therefore are considered to already meet similar requirements. For these pharmacies proof that certification or accreditation is considered proof they meet the requirements of this section of the rule. Paragraphs B and C sets the duties and responsibilities for compliance with the Rules.

A. Each pharmacy permittee shall implement or participate in a continuous quality improvement (CQI) program. A pharmacy permittee meets the requirements of this section (R4-23-622) if it holds a current general, special or rural general hospital license from the Arizona Department of Health Services and is any of the following:

1. *Certified by the Centers for Medicare and Medicaid Services to participate in the Medicare or Medicaid programs;*
2. *Accredited by the Joint Commission on the Accreditation of Healthcare Organizations; or*
3. *Accredited by the American Osteopathic Association.*

B. A pharmacy permittee and pharmacist-in-charge shall ensure that:

1. *The pharmacy develops, implements, and utilizes a CQI program consistent with the requirements of this Section and A.R.S. § 32-1973;*
2. *The data generated by the CQI program, using a QRE Monitoring Program or a Peer Review Error Monitoring Program or a combination of each, is utilized on a regular basis; and*
3. *Training records, policies and procedures, and other program records or documents, other than QRE or error data, are maintained for a*

minimum of two years in the pharmacy or in a readily retrievable manner.

Note that both the pharmacy (permittee) and the pharmacist in charge share responsibility for implementing the programs and utilizing the data generated by the pharmacy's system. Note also that all information must be maintained for a minimum of two years, except the QRE or error data collected. While the pharmacy may need to prove that it collected and used data as part of the CQI system, once the data has been used, it need not be maintained. This is thought to be the best way of maintaining the integrity and confidentiality of the data. Also, once the data is used, there is no need to save it, at least for the purposes of the CQI program.

C. A pharmacy permittee and pharmacist-in-charge shall:

1. Ensure that policies and procedures for the operation and management of the pharmacy's CQI program are prepared, implemented, and complied with;

2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);

3. Document the review required under subsection (C)(2);

4. Assemble the policies and procedures as a written or electronic manual; and

5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

Paragraph C details more of the responsibility given to the pharmacy and the pharmacist in charge.

D. The policies and procedures shall address a planned process to:

1. Train all pharmacy personnel in relevant phases of the CQI program;

2. Institute a QRE Monitoring Program or a Peer Review Error Monitoring Program or a combination of each as the permittee shall determine in its discretion best suits its pharmacy practice and may best be used to reduce medication errors in its operation;

3. Identify and document quality-related events (QRE) or medication errors, depending upon the Monitoring Program selected by the permittee.

4. Record, measure, and analyze data collected to:

a. Assess the causes and any contributing factors relating to QRE the causes, contributing factors or vulnerabilities, and

b. Improve the quality of patient care;

5. Utilize the findings from subsections (D)(2), (3)and (4) to develop pharmacy systems and workflow processes designed to prevent or reduce QRE medication errors; and

6. Communicate periodically, and at least annually, with pharmacy personnel to review CQI program findings and inform pharmacy personnel of any changes made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

Paragraph D sets forth the requirements for the policy and procedure manual in which each pharmacy or pharmacy group describes its system. The Rules mandates that there be a program which meets recognized basic requirement of a CQI program. The Rules do not mandate how the pharmacy sets up or maintains its system, only that each has a program and that it address necessary subjects.

Each pharmacy's system must provide a method to train employees and staff and must incorporate a QRE monitoring system, a peer review error monitoring system or a combination of both. The policies and procedures must provide for the collection and use of the data collected according to the pharmacy's plan. The value of such information is in the improvement made to the program designed to further improve quality. That requires communication of findings and changes to all members of the staff who will be using the system. While most pharmacies will make use of its information much more frequently, changes must be considered at least every two years.

E. *The Board's regulatory oversight activities regarding a pharmacy's CQI program are limited to inspection of the pharmacy's CQI policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.*

F. *Records privileged and confidential*

1. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding.

2. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are confidential and shall not be released, distributed or communicated in any

manner, except as provided by these rule or the permitee's policies and procedures. Recognizing the importance of sharing information with staff, experts, consultants, and others is necessary in reducing medication errors, information used as a part of the permitee's quality program in any manner shall not compromise the confidentiality and privilege of such information.

3. *This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated only as a component of a pharmacy's ongoing quality assurance program and maintained only for that program.*

Paragraphs E and F address the confidential and privileged nature of the data collected as part of each pharmacy's monitoring program. Any monitoring system is only as good as the information collected. In the past, monitoring systems, including those used in pharmacy, have failed because necessary information was not documented on a regular basis. Laws, rules and regulation passed by government and policies and procedures implemented by companies may dictate that required information be reported, but these have proved ineffective absent sufficient consideration given to ways to gain the total involvement of staff and employees. This consideration involves two components – elimination of fear of reporting and sufficient feedback to provide each individual with knowledge that the information is used and that there is a benefit in reporting.

Each pharmacy is encouraged to provide feedback so that the benefits of collecting the information, in terms of reducing medication errors, are apparent to all within the organization. Paragraphs E and F are geared to reducing fears associated with reporting. It is generally agreed that a CQI program is most effective if it is non-punitive in its approach.

Protections provided by the statute are repeated in the rule. All information collected and used strictly for quality purposes is privileged and confidential. Under paragraph E, even the Board of Pharmacy will be denied access to the data. A pharmacist or technician need not fear action or retaliation from the branch of government responsible for licensing because the pharmacist or technician reported a mistake he, she or a co-worker made. While the Board may take action because of a complaint or information discovered thought some other manner, the fact that the Board does not have access to the raw data documented, provides assurance it will

not act on the basis of the data. Discipline for failure to report is possible, but not for the act of reporting.

Privilege protects the collected data from discovery and use in most civil adversarial settings. The legislature recognized that without this protection, pharmacies and pharmacists would be reluctant to collect the information for any purpose, even prevention of future errors. With privilege, even if information came into the hands of others, it cannot be used.

Confidentiality is different. Confidentially protects against and may provide punishment for the disclosure of protected information. In order to use information, pharmacies will need to share at least parts of the information with employees and others. Paragraph F (2) provides that quality data may not be released except as authorized by law or the organization's policy and procedures.

> ***G.*** *An analysis or summary of findings, produced within six months of submission, shall be evidence of compliance with the records and data collection provisions of this section (R4-23-622). A permittee shall not be required to produce data, charts, error reports or findings collected and used in compiling an analysis summary.*
>
> ***H.*** *A pharmacy's compliance with this section shall be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.*

For good reason, the Board is restricted from demanding access to the data generated, whether it be error data or near-miss data. At the same time, under certain circumstances, the Board has the obligation to determine whether a permittee or a pharmacist in charge is following the law, including this section of the rules. Also, a permittee pharmacy or a pharmacist in charge may wish to present evidence to the Board that a particular medication error occurred in spite of its best efforts and that all requirements of this section were complied with, including the collection and use of data. Paragraph H required that the Board consider the pharmacy's and the pharmacist in charge's adherence with this section as a mitigating factor when investigating a medication error. Paragraph I addresses these conflicting needs.

A pharmacy and a pharmacist in charge may prove that required data was collected according to this section of the rules by showing that the information was used. Presentation of "an analysis or summary of findings, produced within six months of submission," would be

presumptive proof. For example, a pharmacy may submit as proof that it collects and uses data generated by its QRE monitoring program by submitting a graph prepared using the data indicating where in the prescription process most near-misses are detected and corrected. The pharmacy could then show what use it made of this information. The data used to generate the chart need not be submitted and could not be requested by the board, but it could review the resulting graph or summary.

[1] See list of committee.

TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 23. BOARD OF PHARMACY

R4-23-622

Continuous Quality Improvement Program

R4-23-110. Definitions

"Continuous quality improvement program" or "CQI program" or "continuous quality assurance program" means a planned process designed by a pharmacy permittee to identify, evaluate, and prevent medication errors.

"Medication error" means any unintended variation from a prescription or drug order. Medication error does not include any variation that is corrected prior to dispensing the medication to the patient or patient's agent, or any variation allowed by law.

"Quality-related event" or "QRE" means both:

A medication error as defined in this section, or

An occurrence during one part of the prescription process that would have resulted in a medication error except that intervention by a pharmacy staff member at another part of the prescription process prevented delivery of the potential medication error to the patient or care-giver.

"Quality-related event monitoring program" or "QRE Monitoring Program" means:

A system of recording, summarizing, and analyzing quality-related events, including medication errors and other occurrences within the definition of QRE in this section. A QRE monitoring program uses statistical process controls and analysis to discover and reduce the risks of vulnerabilities within the prescription process before quality related events and medication errors occur. QRE Monitoring Programs use large numbers of near-misses and errors (QRE) to determine through a statistical analysis what mistakes are most likely and how those risks can be reduced.

Peer Review error monitoring program means:

A system of recording and reviewing each medication error applying root cause analysis to each medication error. A Peer Review Error Monitoring Program shall analysis, collectively and individually, medication errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent or reduce the risk of a recurrence.

R4-23-622 Continuous Quality Improvement Program

A. Each pharmacy permittee shall implement or participate in a continuous quality improvement (CQI) program. A pharmacy permittee meets the requirements of this section (R4-23-622) if it holds a current general, special or rural general hospital license from the Arizona Department of Health Services and is any of the following:

1. Certified by the Centers for Medicare and Medicaid Services to participate in the Medicare or Medicaid programs;
2. Accredited by the Joint Commission on the Accreditation of Healthcare Organizations; or
3. Accredited by the American Osteopathic Association.

B. A pharmacy permittee and pharmacist-in-charge shall ensure that:

1. The pharmacy develops, implements, and utilizes a CQI program consistent with the requirements of this Section and A.R.S. § 32-1973;
2. The data generated by the CQI program, using a QRE Monitoring Program or a Peer Review Error Monitoring Program or a combination of each, is utilized on a regular basis; and
3. Training records, policies and procedures, and other program records or documents, other than QRE or error data, are maintained for a minimum of two years in the pharmacy or in a readily retrievable manner.

C. A pharmacy permittee and pharmacist-in-charge shall:

1. Ensure that policies and procedures for the operation and management of the pharmacy's CQI program are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

D. The policies and procedures shall address a planned process to:

1. Train all pharmacy personnel in relevant phases of the CQI program;
2. Institute a QRE Monitoring Program or a Peer Review Error Monitoring Program or a combination of each as the permittee shall determine in its

discretion best suits its pharmacy practice and may best be used to reduce medication errors in its operation;

3. Identify and document quality-related events (QRE) or medication errors, depending upon the Monitoring Program selected by the permittee.

4. Record, measure, and analyze data collected to:

   a. Assess the causes and any contributing factors relating to QRE the causes, contributing factors or vulnerabilities, and

   b. Improve the quality of patient care;

5. Utilize the findings from subsections (D)(2), (3)and (4) to develop pharmacy systems and workflow processes designed to prevent or reduce QRE medication errors; and

6. Communicate periodically, and at least annually, with pharmacy personnel to review CQI program findings and inform pharmacy personnel of any changes made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

E. The Board's regulatory oversight activities regarding a pharmacy's CQI program are limited to inspection of the pharmacy's CQI policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

F. Records privileged and confidential

1. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding.

2. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are confidential and shall not be released, distributed or communicated in any manner, except as provided by these rule or the permitee's policies and procedures. Recognizing the importance of sharing information with staff, experts, consultants, and others is necessary in reducing medication errors, information used as a part of the permitee's quality program in any manner shall not compromise the confidentiality and privilege of such information.

3. This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated only as a component of a pharmacy's ongoing quality assurance program and maintained only for that program.

G. An analysis or summary of findings, produced within six months of submission, shall be evidence of compliance with the records and data collection provisions of this section (R4-23-622). A permittee shall not be required to

produce data, charts, error reports or findings collected and used in compiling an analysis summary.

H. A pharmacy's compliance with this section shall be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

Cheryl Frush

From: Janet Elliott [Janet@azretailers.com]

Sent: Monday, August 18, 2008 1:04 PM

To: director@azpharmacy.org; ken@kenbakerconsulting.com; sarju.patel@cigna.com; misty.vo@bannerhealth.com; DJohnston@AzHHA.Org; mdboesen@cox.net; 'Terri L. Warholak'; 'Elizabeth Baskett'

Cc: hwand@azpharmacy.gov; dwright@azpharmacy.gov; cfrush@azpharmacy.gov

Subject: CQA Draft Rules - Draft dated July 2008

Importance: High

Dear CQA Task Force Members,

Following review of the most recent draft rules dated July 2008, ACPC member pharmacies remain opposed to language that includes the tracking of "near misses". ACPC members believe that the proposed language is going away from the direction of the legislation which states that:

each pharmacy shall implement or participate in a continuous quality assurance program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors.

ACPC supported HB 2255 with the understanding that the intent of the legislation was to ensure that all pharmacies implement or participate in a continuous quality assurance program. We supported the bill for the protection for discovery and the assurance that pharmacies would be allowed the flexibility to incorporate the program into their company's existing policies and procedures.

Attached is the ACPC mark-up draft copy that was submitted to the task force at the last task force meeting held on May 28, 2008. Our members continue to believe that the attached draft would simplify the language while meeting the requirements and intent of the statute and would allow pharmacy corporations to determine how to best run the program for their pharmacies.

Thank you,
Janet Elliott
Director, Pharmacy Affairs
Arizona Community Pharmacy Committee
224 West 2nd Street
Mesa, AZ 85201
480-833-0009 (office)
480-833-0011 (fax)
janet@azretailers.com

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-622. Continuous Quality Improvement Program

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

Removed definitions not changed

"Continuous quality improvement program" or "CQI program" means a planned process designed by a pharmacy permittee to identify, evaluate, and prevent medication errors.

"Medication error" means any unintended variation from a prescription or drug order. Medication error does not include any variation that is corrected prior to dispensing the medication to the patient or patient's agent, or any variation allowed by law.

"

Comment: Because of the documentation, analysis and recordkeeping required in section D, ACPC continues to oppose the requirement to include "near misses". Strike the definition of "Quality-related event" and confine the program to medication errors.

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-622. Continuous Quality Improvement Program

A. Each pharmacy permittee shall implement or participate in a continuous quality improvement (CQI) program. A pharmacy permittee meets the requirements[1] of this section if it holds a current general, special or rural general hospital license from the Arizona Department of Health Services and is any of the following:

1. Certified by the Centers for Medicare and Medicaid Services to participate in the Medicare or Medicaid programs;
2. Accredited by the Joint Commission on the Accreditation of Healthcare Organizations; or
3. Accredited by the American Osteopathic Association.

B. A pharmacy permittee and pharmacist-in-charge shall ensure that:

[1] Sub-committee had some divergence of opinion as to whether a hospital pharmacy is by statute exempt from the entire rule, or just the implementation portion of the rule. Agreed this is a Board of Pharmacy question.

1. The pharmacy develops, implements, and utilizes a CQI program consistent with the requirements of this Section and A.R.S. § 32-1973;
2. The medication error data generated by the CQI program is utilized on a regular basis[2],; and
3. Training records, policies and procedures, and other program records or documents, other than medication error data, are maintained for a minimum of two years in the pharmacy or in a readily retrievable manner.

Comment: Delete quality-related event and replace with medication error.

Comment: Delete then and replace with than

Comment: Delete QRE data and replace with medication error data.

C. A pharmacy permittee and pharmacist-in-charge shall:
1. Ensure that policies and procedures for the operation and management of the pharmacy's CQI program are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

D. The policies and procedures shall address a planned process to:
1. Train all pharmacy personnel in relevant phases of the CQI program;
2. Identify and document medication errors;
3. Record, measure, and analyze data collected to:
   a. Assess the causes and any contributing factors relating to medication errors, and
   b. Improve the quality of patient care;
4. Utilize the findings from subsections (D)(2) and (3) to develop pharmacy systems and workflow processes designed to prevent or reduce medication errors; and
5. Communicate periodically, and at least annually, with pharmacy personnel to review CQI program findings and inform pharmacy personnel of any changes made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

Comment: Delete quality-related events and replace with medication errors.

Comment: Delete QRE and replace with medication errors.

Comment: Delete QRE and replace with medication errors.

E. The Board's regulatory oversight activities regarding a pharmacy's CQI program are limited to inspection of the pharmacy's CQI policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

F. A pharmacy's compliance with this section shall be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

[2] The committee felt the data needed to be used on a regular basis in order to qualify as a continuous quality improvement program. A pharmacy should improve using a system to detect vulnerabilities based upon trends and facts. Some thought this should be specified as "no less than quarterly" while others felt that pharmacies should be allowed flexibility in determining when and how often a review should occur, depending on how the data is used.